REMARKS

This Amendment is responsive the Examiner's Answer before the Board of Patent Appeals and Interferences, which raised new issues. Applicant has re-opened prosecution by virtue of this response, in compliance with 37 CFR 41.39(b)(1).

Applicant has amended claims 12, 13, 22 and 32 to address the new issues raised in the Examiner's answer with respect to 35 U.S.C. §101. Applicant has also canceled claim 31, and added new dependent system claims 38-49. New dependent system claims 38-49 depend upon independent claim 37, and recite features similar to dependent method claims 23-30 and 33-36. New dependent claims 38-49 are relevant to the new rejections insofar as they present the features of claims 23-30 and 33-36, which are newly rejected under 35 U.S.C. §101, in the context of system claim 37, which is the only previous claim that was not newly rejected under35 U.S.C. §101.

Claims 12-30 and 32-49 are now pending.

New issues under 35 U.S.C. §101

The Examiner's Answer raised new rejections, prompting this Amendment that re-opens prosecution. Specifically, the Examiner indicated that claims 12-36, as previously presented, were directed to non-statutory subject matter under 35 U.S.C. §101. In response Applicant has amended claims 12, 13, 22 and 32 to address any possible concerns regarding compliance with 35 U.S.C. §101. These claim amendments are being made to advance prosecution and are not any admission regarding the propriety of the rejections.

Independent claims 12 and 13 have each been amended to be in statutory compliance with 35 U.S.C. 112, sixth paragraph, by invoking means plus function language. Claim 12 now satisfies 35 U.S.C. §101 as a system reciting means plus function limitations in compliance with 35 U.S.C. 112, sixth paragraph. Claim 13 also satisfies 35 U.S.C. §101 as a system reciting means plus function limitations in compliance with 35 U.S.C. 112, sixth paragraph.

Independent claim 22 has been amended to recite steps that are performed "by a computer." In this way, claim 22 now clearly complies with 35 U.S.C. §101 for a method claim insofar as claim 22 satisfies the first prong (i.e., the "machine prong") of the so-called machine or transformation test articulated by the Federal Circuit for compliance with 35 U.S.C. §101. Applicant reserves further comment as to whether

claim 22 may also satisfy the second prong (i.e., the "transformation prong") of this test.

New dependent system claims 38-49 have been added at this time, and depend upon independent claim 37. New dependent claims 38-49 recite features similar to dependent method claims 23-30 and 33-36, and are being presented due to the new rejections of such features in the context of method claim 22. Independent claim 37 was not rejected under 35 U.S.C. §101, and therefore, new dependent claims 38-49 should also comply with 35 U.S.C. §101.

New issues under 35 U.S.C. §112, second paragraph

The Examiner's Answer also raised new rejections under 35 U.S.C. §112, second paragraph, but these appear to be related to the rejections under 35 U.S.C. §101. The Examiner indicated that the preambles of claims 12-21 recite computer-implemented systems, but that the body of the claims does not tie the systems to a computer.

The current amendment to claim 12 should more clearly tie the body of claim 12 to the preamble that recites a computer-implemented system. Applicant disputes that the preamble and body were previously indefinite, but notes that the current amendment to claim 12 should address any concerns on this issue.

With respect to claims 13-21, which are now in compliance with 35 U.S.C. §112, sixth paragraph, Applicant does not see any inconsistencies with the preamble and the body of these claims. In contrast to the Examiner's assertions, the preamble of claim 13 recites "A system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising." Nothing in this preamble is unclear or inconsistent with the body of claim 13, which recites features in means plus function format, in compliance with 35 U.S.C. §112, sixth paragraph. The rejections of claims 13-21 under 35 U.S.C. §112, second paragraph, should be withdrawn.

Observations Regarding the Current Rejections under 35 U.S.C. 103(a) and Applicant's Previous Arguments

Applicant requests clarification by the Examiner's comments in the Examiner's Answer re-stating some or all of the same arguments without addressing any of Applicant's detailed replies to such arguments. For example, the Examiner provided

four headings of "response to arguments," which appear to be a verbatim copy of previous comments by the Examiner in the Final Office Action.

Applicants request the Examiner reconsider the detailed analysis in Applicant's Appeal Brief.

For example in the paragraph labeled "(1)" in the Response to Arguments section of the Examiner's Answer, the Examiner stated that Applicant is arguing that Mushabac and Blume references cannot be combined since they are non-analogous. Although Applicant agrees that Mushabac and Blume are non-analogous, Applicant's arguments in the Appeal Brief articulate features of Applicant's claims that are missing in Mushabac or Blume or any purported combination of these references. Applicant's argument is not merely that Mushabac and Blume are non-analogous.

In particular, nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or techniques that generate a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

As another example, in the paragraph labeled "(2)" in the Response to Arguments section of the Examiner's Answer, the Examiner cited to sections of the Sullivan Provisional that fail to support the Examiner's conclusions. Applicant explained, in detail in the Appeal Brief, that some of the cited material from the Sullivan Provisional is not even included in the Sullivan patent (namely FIG. 23). In addition, Applicant also explained that the other cited portions of the Sullivan Provisional are not the same as or similar to the material of Sullivan relied upon by the Examiner in the rejections. Moreover, Applicant also explained that like FIG. 23 of Sullivan, the relied upon material from the Sullivan Provisional fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "selecting for a given health care facility a plurality of health care delivery practices associated with the surgical

procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37.

As yet another example, in the paragraph labeled "(3)" in the Response to Arguments section of the Examiner's Answer, the Examiner indicated that FIG. 16 of the Afsah Provisional supports the passage at column 6, lines 9-20, of Afsah. However, Applicant explained in detail in the Appeal Brief that FIG. 16 of the Afsah Provisional is merely a graph that is not even described in the Afsah Provisional. Moreover, one or ordinary skill in the art would find no support for the subject matter of column 6, lines 9-20, in FIG. 16 of Afsah. Accordingly, the relied upon passage at column 6, lines 9-20, of Afsah is not entitled to the Afsah Provisional date, and the cited passage of Afsah at column 6, lines 9-20 is not prior art to Applicant's claims.

Furthermore, regardless of whether Afsah is entitled to the priority date of the Afsah Provisional, Applicant also noted in the Appeal Brief that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The Examiner also did not appear to address this issue in the Examiner's Answer.

As yet another example, the Examiner's Answer does not appear to even address dependent claims 34-36, which were argued under a separate heading in the Appeal Brief. Like the Final Office Action, the Examiner's Answer merely asserted that: "as per claims 26-35 and 37,[1] these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect.

Applicant presents the arguments below. Applicant respectfully requests that the Examiner reconsider the arguments, and allow the claims.

Rejections under 35 U.S.C. 103(a)

Claims 12-22 and 26-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over a six-way combination of references. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over a seven-way combination of

---

[1] Relative to a previous Office Action that also mentioned claim 36 in this section, in the Final Office Action (and again in the Examiner's Answer), the Examiner had changed this portion of the discussion to state "as per claims 26-35 and 37 these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." The Examiner mentioned claim 36 with claim 22, but again failed to address any of the features of claim 36 in any substantive discussion.

references. Specifically, claims 12-22 and 26-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe and in further view of Blume and in further view of Mushabac and in further view of Sullivan and in further view of Afsah. Claims 23-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mangram in view of Ormond-Walshe and in further view of Blume and in further view of Mushabac and in further view of Sullivan and in further view of Afsah and in further view of Jacober.

Consistent with the previously filed Appeal Brief, Applicant will focus primarily on the features recited in claim 22. Applicant's independent claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure. The method has been currently amended to require certain steps be performed by a computer, in order to address any concerns regarding 35 U.S.C. §101. The method of claim 22 comprises selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, and evaluating a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure. The method further comprises storing data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

Applicant's independent claim 37 recites features that are similar to those of claim 22, but recites such features in means plus function format, in the context of a system. New dependent claims 38-49 have been added consistent with dependent claims 23-30 and 33-36. Applicant's independent claims 12 and 13 also recite features that are similar in many respects to those of claim 22, but claims 12 and 13 are more specific in requiring a perioperative process map. For purposes of this appeal, as mentioned above, Applicant will primarily focus the following discussion on claim 22. Similar arguments also apply to independent claims 37, 12 and 13.

In the current rejections of claims 12-22 and 26-37, the Examiner cited Mangram as teaching "evaluating a practice associated with a surgical procedure that

13

poses an infection risk," as required by claim 22. The Examiner recognized that Mangram fails to disclose "storing data indicative of the practice associated with the surgical procedure," as required by claim 22, but cited Ormond-Walshe as teaching this feature. The Examiner concluded that it would have been obvious to modify the techniques of Mangram concerning prevention of infection risks with computerized databases in the medical field, as taught by Ormond-Walshe in order to arrive at a technique that evaluates a practice associated with a surgical procedure that poses an infection risk, and stores data indicative of the practice associated with the surgical procedure.

Next, the Examiner recognized that the combination of Mangram and Ormond-Walshe still fails to disclose or suggest identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice, as required by claim 22. However, the Examiner stated that this feature is well known in the art as evidenced by Blume and Mushabac.

Specifically, the Examiner recognized that the combination of Mangram and Ormond-Walshe fails to disclose or suggest identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice (independent claims 22 and 37). Similarly, the Examiner also recognized that the combination of Mangram and Ormond-Walshe fails to disclose or suggest generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule (independent claims 12 and 13). However, the Examiner stated that these features are well known in the art, as evidenced by "the combined teachings of Blume and Mushabac."

In contrast to the Examiner's allegations, however, nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or techniques that generate a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

14

The entire passage of Blume relied upon by the Examiner is reproduced below:

Data received from localizers 20, and the processing by processor 32 to present a graphical representation on display 40 of the magnetic field produced by magnet 14 must be fast enough to provide "real-time" feedback for a surgeon; i.e., the feedback must be rapid enough to allow decisions to be made during a surgical procedure involving the movement of the implanted magnetic device 30. The method of Procrustes is used to compute the 4.times.4 rigid body transformation between coordinates in the imaging system and coordinates in the localizer system. Thereafter, the 4.times.4 matrix may be applied to transform a pre-stored representation of a magnetic field into a magnetic field having the position and orientation sensed by localizers 20 using standard programming techniques on a presently-available Intel PENTIUM.RTM.-based processor (such as a typical PC), or a Silicon Graphics workstation, with the transformation being accomplished in sufficient time to provide a display that is updated rapidly enough for surgical purposes. Column 7, lines 16-33.

Contrary to the Examiner's conclusion, this teaching in Blume has no relevance with respect to the features recited in Applicant's claims, which concern computer-implemented systems for managing the risk or occurrence of surgical site infection. In contrast to Applicant's claims, the above passage of Blume describes the use of magnets in a surgical procedure to provide the surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device. Thus, this teaching of Blume has no relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection, and lacks any teaching pertinent to such endeavors.

Furthermore, the teaching of Blume cited above clearly lacks any suggestion of identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). Accordingly, the Examiner's contentions with respect to Blume are factually incorrect.

Similarly, the teaching of Mushabac relied upon by the Examiner is also irrelevant to the features of Applicant's claims. The relied upon passage of Mushabac is reproduced below.

Advantageously, the computer provides the dental practitioner operating the dental tool with an alert signal regarding deviation between an actual position and orientation of the tool during the use of the tool on the patient and the optimal position and the optimal orientation, as determined prior to the dental

15

> operation. The alert signal may take the form of an auditory signal, for example, a verbal message or instruction synthesized by the computer. Alternatively or additionally, the alert signal may include a visual indication provided on the monitor. An alert signal may also be provided in a practice operation, to indicate to the operator a deviation or a conformity of the practice instrument to the predetermined, recommended position and orientation thereof. Column 4, lines 56 to column 5, line 2.

This passage of Mushabac also lacks any relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection. Instead, this passage of Mushabac describes a dental tool that generates an audible or visible alert when the dental tool is mis-positioned.

An alert that is generated when a dental tool is mis-positioned is nothing akin to the features of Applicant's claims, e.g., identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13). A person of ordinary skill in the art would not have had any rational reason to modify any computer-implemented system for managing the risk or occurrence of surgical site infection (e.g., per a combination of Mangram and Ormond-Walshe) to generate a flag when a surgical procedure is not in compliance with a rule, or to identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure.

Indeed, the teachings of Blume and Mushabac are completely unrelated to those of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Blume. To be sure, Blume describes a system that provides a surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device, and Mushabac describes a dental tool that generates an alert when the tool is mis-positioned. These teachings concern totally different endeavors than those of Mangram and Ormond-Walshe and include no teachings pertinent to the management of infection in surgical procedures.

16

Furthermore, even if the alert generation in Mushabac could be reasonably construed as generating a flag, the alert in Mushabac occurs when a dental tool becomes misaligned, and has no relevance to compliance of a surgical procedure with a rule, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure.

In short, neither Mushabac nor Blume discloses or suggests computerized identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 22 and 37) or computerized generation of a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13).

To the extent that Mushabac teaches the generation of an alert, the alert of Mushabac relates to dental tool misalignment, and has no relevance to the management of risks of surgical site infection incident to the surgical procedure. Furthermore, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Blume. Indeed, positioning of implanted magnetic devices, per Blume, and dental tools that generate alerts when the tools are mis-positioned, per Mushabac, are not reasonably pertinent to the teachings of Mangram concerning prevention of surgical site infection, nor reasonably pertinent to the teaching of Ormond-Walshe concerning computerized databases for infection control. For each of these reasons, the current rejections must be reversed.

Notwithstanding theses deficiencies in the Examiner's position regarding Mangram and Ormond-Walshe in view of Mushabac and/or Blume, Applicant previously filed an RCE at the Examiner's request (see the Examiner's suggestion in the Office Action mailed June 5, 2007) and attempted to modify the claims specifically to address the Examiner's concerns at that time. However, in response to these attempts to advance the Application, the Examiner applied additional references (namely the Sullivan and Afsah references), which appear to have little or no relevance to the systems and features that Applicant is attempting to patent. Furthermore, the relied upon portions of Sullivan and Afsah are not even prior art to Applicant's claims.

Specifically, the Examiner recognized that a combination of Mangram, Ormond-Walshe, Blume and Mushabac fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of

17

measurable risk of surgical site infection are selectable for a given health care facility," as specifically required by claims 12 and 13. Claims 22 and 37 similarly require selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection.[2] For this feature, the Examiner cited Sullivan (specifically section **[0055]**) and argued that it would have been obvious to further modify the combination of Mangram, Ormond-Walshe, Blume and Mushabac in view of this passage of Sullivan.

Applicant traverses this portion of the Examiner's argument for two reasons. First, the cited passage of Sullivan does not qualify as prior art to Applicant's claims. Second, the cited passage of Sullivan appears to be wholly irrelevant to the feature "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility."

Section **[0055]** of Sullivan is reproduced below:

> **[0055]** **FIG. 23** is another illustration of a screen display of a prescription medicine template.

The Examiner's assertion of Sullivan is incorrect. This cited section of Sullivan in no way suggests any feature even remotely akin to "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37. On the contrary, FIG. 23 of Sullivan shows nothing more than a screen shot of a prescription medicine template that has no relevance to a surgical procedure. Moreover, nothing in FIG. 23 appears to be selectable for a given health care facility, in any way.

In addition, section **[0055]** of Sullivan is not even prior art to Applicant's claims. The application for the Sullivan patent was filed on November 2, 2001, which is after Applicant's filing date of December 4, 2000. While Sullivan claims priority to a provisional application filed on November 2, 2000 ("the Sullivan Provisional"), the

---

[2] It should be noted that in the analysis of claim 22, the Examiner failed to even address the step of claim 22 that recites *selecting for a given health care facility* a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection.

Sullivan Provisional only includes sixteen figures. Section **[0055]** of Sullivan and FIG. 23 are not included in the Sullivan Provisional, and there appear to be no other portions of the Sullivan Provisional that would correspond to or otherwise provide support for section **[0055]** or FIG. 23. Accordingly, the cited passage of Sullivan is not entitled to the December 4, 2000 priority date.

In the Final Office Action, the Examiner stated that section **[0055]** and FIG. 23 are supported on page 19, lines 13-20, of the Sullivan Provisional. This section of Sullivan is reproduced below:

> The health care professional has access to a medical risk database 14 maintained on a data storage medium. The database 14 associates certain medical data in the patient data record 22 with additional medical care. The health care professional uses a data processor 16 to compare the medical data presented by the patient data record 22 with the medical data in the medical risk database 14 to identify whether medical data presented by the patient is associated with a risk of missed medical care opportunity. If so, information about additional medical care that would reduce the risk of a missed medical care opportunity is presented to the attending medical health care professional.

Clearly, this cited material from the Sullivan Provisional is not the same as or similar to the material of Sullivan relied upon by the Examiner. Nothing in this section includes any discussion of content similar to that of FIG. 23 of Sullivan. Moreover, like FIG. 23 of Sullivan, this material from the Sullivan Provisional fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by claims 12 and 13 or "selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection" as required by claims 22 and 37. On the contrary, the passage above describes a medical risk database that stores medical risks associated with a patient, but fails to suggest anything related to surgical procedures. In addition, the passage above fails to describe anything that is selectable for a given health care facility, in any way. The rejection of any claims based on the cited teaching of Sullivan is clearly erroneous, and should be overturned.

In the final Office Action, the Examiner also recognized that the combination of Mangram, Ormond-Walshe, Blume, Mushabac and Sullivan fails to suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with

delivery of corresponding health care delivery practices" as required by all pending independent claims. For this feature, the Examiner cited column 6, lines 9-20, of Afsah. However, Afsah was filed after Applicant's current case, and this relied upon passage of Afsah is not supported by the Afsah Provisional date.

In the Office Action, the Examiner indicated that FIG. 16 of the Afsah Provisional supports the passage at column 6, lines 9-20, of Afsah. However, FIG. 16 of the Afsah Provisional is merely a graph that isn't even described in the Afsah Provisional. One or ordinary skill in the art would find no support for the subject matter of column 6, lines 9-20, in FIG. 16 of Afsah. Accordingly, the relied upon passage at column 6, lines 9-20, of Afsah is not entitled to the Afsah Provisional date, and the cited passage of Afsah at column 6, lines 9-20 is not prior art to Applicant's claims.

Furthermore, regardless of whether Afsah is entitled to the priority date of the Afsah Provisional, Applicant also notes that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The passage of Afsah at column 6, lines 9-20, is reproduced below:

> Although the above method for determining the bench-
> 10 mark value of a particular indicator is preferred, there are
> other ways of identifying a benchmark value. For example,
> either the limit value of an indicator mandated by compli-
> ance regulations, or an historical baseline value can be used
> as the benchmark value for an indicator. Also the quartile
> 15 approach can he used where the data group of indicator
> values is divided into quartiles and the worst value from the
> best quartile is selected as the benchmark value. Similarly,
> the best 10% approach can be used where the best 10% of
> the indicator value data group is selected and the worst value
> 20 of the best 10% is designated as the benchmark value.

In this case, the so-called "benchmark value" is a benchmark for air admissions, used to help measure environmental performance. Indeed, Afsah is not even relevant to health care, much less the features of Applicant's claims. The passage above does not suggest any compliance indicator that indicates compliance with the one or more health care practices, as required by Applicant's claims, much less a compliance indicator that quantifies a measure of quality associated with delivery of corresponding health care delivery practices. Accordingly, for yet these additional reasons, i.e., that the cited portion of Afsah is not prior art to Applicant's invention and not even relevant to health

care, much less the features of Applicant's claims, the current rejections of all pending claims are improper and should be reversed.

Dependent claims 34-36

Applicant again notes that dependent claims 34-36 have not yet been addressed in any Office Action. Like the Final Office Action, the Examiner's Answer merely asserted that: "as per claims 26-35 and 37, these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect.

Relative to a previous Office Action that also mentioned claim 36 in this section, in the Final Office Action (and the Examiner's Answer), the Examiner had changed this portion of the discussion to state "as per claims 26-35 and 37 these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." The Examiner mentioned claim 36 with claim 22, but again failed to address any of the features of claim 36 in any substantive discussion.

In any case, Claims 34-36 do not appear to have been addressed at any time. Indeed, claims 34-36 present features that the Examiner has not considered or addressed in any Office Action. Claims 34-36 read as follows:

> Claim 34: The method of claim 22, further wherein the compliance indicator defines a value within a pre-established quality scale.

> Claim 35: The method of claim 34, wherein the quality scale ranges from 1 to 10.

> Claim 36: The method of claim 22, further comprising generating a report that represents a compilation of measurement data associated with the surgical procedure.

None of these features of claims 34-36 have even been addressed in any Office Action to date, and for this reason, the rejections must be reversed.

Dependent claims 23-25

In the rejections of dependent claims 23-25, the Examiner's Answer referred to Jacober and clarified that these claims were being rejected based on a seven-way combination of Mangram in view of Ormond-Walshe and in further view of Blume and in further view of Mushabac and in further view of Sullivan and in further view of Afsah and in further view of Jacober.

Claims 23-25 are dependent upon claim 22. Claim 23 clarifies that identifying when the data indicative of the given practice is not in compliance with the rule comprises generating a flag for the data. Claim 24 further requires prompting medical personnel to take further action when the flag is generated. Claim 25 further requires clearing the flag when the further action is taken.

Nothing in Jacober or any of the applied references discloses or suggests identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure, which is required by claim 22 from which claims 23-25 depend. Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Jacober with the teaching of Mangram or Ormond-Walshe as theses teaching are totally unrelated and concern totally different areas of endeavor.

The Jacober reference describes a medication regimen container and system. In particular, Jacober describes a medication dispensing unit that can be programmed to signal proper medication dosages to a user, and the times of such dosages. Nothing in Jacober discloses or suggests the identification of when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Indeed, Jacober does not even relate to surgical procedures, whatsoever.

Applicant disputes the Examiner's conclusions that a person of ordinary skill in the art would have been motivated to (or found any rational reason) to have modified the teachings of Mangram and Ormond-Walshe in further view of Jacober to arrive at a computerized system for managing surgical site infection incident to the surgical procedure by generating flags when a given health care practice associated with the surgical procedure is not in compliance with a rule.

Indeed, the teaching of Jacober is completely unrelated to that of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Jacober. To be sure, Jacober concerns a medical regimen container for managing the dispensing of medication, and has no relevance in the field of surgical procedures whatsoever, much less management of risks of surgical site infection incident to the surgical procedure. Thus, even if Jacober could be reasonably construed as generating a flag,

the flag of Jacober relates to the dispensation of medication from a programmable container, and has no relevance to a surgical procedure nor the management of risks of surgical site infection incident to the surgical procedure.

CONCLUSION

Applicant has presented many arguments, and respectfully requests reconsideration and allowance of all pending claims. To the extent any rejections are maintained, Applicant respectfully requests that the Examiner respond to the arguments advanced by Applicant, and not simply restate the same comments that Applicant has attempted to address and refute.

Applicant believes that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-3723. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

/Nancy M. Lambert/

Nancy M. Lambert
Registration No. 44,856
Attorney for Applicants

NML:jlh\#703499 Response to Examiner's Answer
Office of Intellectual Property Counsel
3M Innovative Properties Company
P.O. Box 33427
St. Paul, Minnesota 55133-3427
(651) 733-2180
Facsimile: (651) 736-3833

Dated: June 3, 2009